

REMARKS***Status of the claims***

Claims 1-65 were pending in this application. By virtue of this amendment, claims 2, 17, 32, 35, 42, 45, and 58 have been canceled, and claims 1, 3-4, 16, 18-19, 28-31, 33-34, 36-41, 43-44, 46-54, 57, and 59-60 have been amended. Accordingly, claims 1, 3-16, 18-31, 33-34, 36-41, 43-44, 46-57, and 59-65 are currently pending.

The amendments to the claims are supported, for example, by the claims as originally filed and in the Summary of the Invention section of the specification. Accordingly, no new matter has been added by the foregoing amendments.

With respect to claim amendments, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Restriction requirement

The Office has required restriction to one of the following inventions under 35 U.S.C. §121:

Group 1: Claims 1-40, drawn to methods of transfecting a polynucleotide to cells by administering to the cells a combination of: (i) at least one polynucleotide; (ii) a cationic lipid, a cationic polymer, a dendrimer, or a combination thereof; and (iii) a solubilized cholesterol preparation.

Groups 2-24: Claims 50-54, drawn to method of treating bladder cancer by intravesicular administration to bladder cells *in vivo* of a pharmaceutical agent comprising: (i) at least one polynucleotide comprising an expression vector encoding one of the following: interleukin-1 (IL-1), interleukin-2 (IL-2), interleukin-6 (IL-6), interleukin-9 (IL-9), interleukin-11 (IL-11), interleukin-12 (IL-12), interleukin-13 (IL-13), interleukin-18 (IL-18), interferon-alpha, interferon-beta, interferon-gamma (IFN-gamma), granulocyte-macrophage colony stimulating factor (GMCSF), granulocyte colony stimulating factor (GCSF), macrophage colony stimulating factor (MCSF), heat shock protein (HSP), p52, an antagonist of vesicular endothelial cell growth factor (VEGF), a tissue inhibitor of metalloproteinases (TIMP), a fibronectin receptor, or an expression vector encoding one of the following combinations: IL-2 and GMCSF, IL-2 and IFN-gamma, or IL-2, GMCSF, and IFN-gamma; (ii) a cationic lipid, cationic polymer, a dendrimer, or combination thereof; and (iii) a solubilized cholesterol preparation. The Examiner indicated that Claims 41-49, 55, and 56 link the inventions of groups 2-24, and that upon allowance of the linking claim(s), the restriction requirement with regard to the linked inventions would be withdrawn and any claim(s) depending from or otherwise including all of the limitations of the allowable linking claim(s) would be examined.

Group 25: Claims 57-65, drawn to a transfection composition comprising: (i) a polynucleotide; (ii) a cationic lipid, a cationic polymer, a dendrimer, or a combination thereof; and (iii) a solubilized cholesterol preparation.

Applicants hereby elect group 25 without traverse. Applicants expressly reserve their right under 35 U.S.C. §121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

In response to the requirement under §121 to elect a single disclosed species for searching purposes, Applicants elect the species of cationic lipid (claims 1-5, 7-20, 22-36, 38-46, 48-61, and

63-65 as originally presented). Applicants note that upon allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species. Applicants request that, upon the allowance of a generic claim, the remainder of the species be included as permitted by 37 C.F.R. §1.141(a).

Applicants request examination of the elected subject matter on the merits.

Request for rejoinder of method claims

Applicants respectfully requests rejoinder of the withdrawn method claims upon allowance of the elected composition claims, in accordance with MPEP §821.04 (“Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. . . . However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.”). Claims 1, 3-16, 18-31, 33-34, 36-41, 43-44, and 46-56 as amended depend from the composition claims pending in the instant application. Applicant respectfully requests rejoinder of these method claims upon allowance of the composition claims from which they depend.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 578762000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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